Testimony before the Senate Special Committee on Aging On Medicare's End Stage Renal Disease Program Submitted by the Renal Physicians Association

The RPA is the national representative for physicians engaged in the study and management of patients with renal disease, and our goal is to ensure optimal care under the highest standards of medical practice. RPA appreciates the opportunity to provide written testimony to the Special Committee on Aging, and our organization is available as a resource to Committee as it continues its review of the quality of care provided to the nation's End Stage Renal Disease (ESRD) patients. RPA's testimony will discuss our positions on the issues raised by the Committee in its request for input, primarily focusing on regulatory oversight of the ESRD program, and in the context of those positions will offer recommendations for improvement where appropriate.

Overview and History

The RPA has long supported appropriate oversight and accountability of providers, nephrologists, allied health professionals, and payers of ESRD services in the context of quality of patient services. The RPA views the routine measurement of clinical outcomes as the infrastructure of quality. These outcomes should be tied to achievable expectations of performance that have the potential to enhance the quality and quantity of patients' lives and meet their physical and emotional needs. All this should be achieved recognizing fiduciary responsibility to the payers of the ESRD Program.

Examples of the RPA's commitment to quality of dialysis services includes our development and dissemination of clinical practice guidelines for nephrologists, dialysis units, and patients. We were the first to offer minimum standards for the amount of hemodialysis and expanded these offering best practices for dialyzer reuse. Moreover, the RPA assumed a substantial partnership role with HCFA in translating the guidelines into national performance measures. Recognizing an opportunity to expand health literacy, the RPA developed a sentinel practice guideline offering guidance for shared decision making about initiating and discontinuing dialysis. Other relevant initiatives include the development and distribution of recommendations for the minimum frequency of physician visits to the dialysis unit, a description of the scope of work for a dialysis unit medical director, and a documentation tool for fulfillment of the scope of work under the nephrologist's monthly capitated payment. We would be pleased to provide any of these documents at the Committee's request.

RPA Positions on Quality Oversight and Improvement

Regarding the specific issues under review by the Special Committee, the RPA has developed and distributed position papers on the following topics in recent years: 1) ESRD patient protection in managed care organizations in which safeguards for this vulnerable patient population are articulated, 2) support for the exclusion of ESRD patients from managed care plans until greater patient protection is implemented and the AAPCC is adjusted, and 3) principles for dialysis unit accreditation and certification that urge review at regular frequencies and that focus on patients' outcomes, rather than operational processes. The principal thrusts of these three positions are summarized as follows, and the complete documents are appended to this testimony:

ESRD Patient Protections in Managed Care - RPA believes that in order to protect the rapidly expanding managed care population in the United States, particularly vulnerable sub-groups such as those with ESRD, legislation establishing patient protections must be enacted. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Foremost, the system must define

and evaluate processes of enrollment and care where the patient and family understand the ramifications of a particular decision. RPA acknowledges that when cautiously and appropriately administered, managed care can provide enhanced efficiencies of care delivery. However, patients often get lost in the fray of efficiency and fall victim to a well-intended but flawed system. The physician must remain the patient's advocate in an increasingly sophisticated system. Early prevention can often save both costs and morbidity. For chronically ill patient populations such as those with ESRD or those with conditions that are often precursors to ESRD such as diabetes and hypertension, the limitations inherently present in managed care can have a tangibly negative effect, including reduced quality or loss of life.

ESRD Patient Participation in Managed Care Plans - Currently, RPA opposes a repeal of Section 1876 of the Social Security Act, which specifically prohibits Medicare ESRD beneficiaries from participating in managed care plans. However, the issue of ESRD patient participation in managed care plans has recently come under increased scrutiny, and therefore RPA believes this subject merits reevaluation. In order for ESRD patients to safely participate in managed care plans, the RPA believes that: (1) A quality oversight program must be implemented that includes continuous quality improvement methodologies such as clinical practice guidelines, clinical performance measures, and integrated information systems. Quality improvement processes should encompass the current ESRD Network system and should focus on actual implementation of CQI methodologies at both the Network level and the facility level. A national committee should be established to oversee these CQI efforts. Legislative proposals should include emphasis on patient surveys and outline the critical success factors needed for QI implementation at the network and dialysis facility level; (2) Modification of the AAPCC must occur first as many of the other difficulties occurring in Medicare managed care flow from inadequate reimbursement for these groups of patients. Appropriate adjustment for case-mix variability that provides sufficient reimbursement for both complex and relatively stable ESRD patients will allow the sponsors of these delivery systems to provide an expanded level of benefits to vulnerable patients while maintaining fiscal viability; and (3) Any legislative proposal to repeal the 1876 prohibition must be delayed for a minimum of two years to allow for full implementation of the CQI oversight program and modification of the AAPCC. In the event that the CQI and AAPCC proposals are not implemented, the ban must not be repealed.

Improving the Dialysis Facility Accreditation and Certification Process - The RPA supports the accreditation, certification and licensure of dialysis facilities as a visible means of ensuring accountability, and in order to accomplish these functions appropriately, increased federal funding is necessary. The RPA believes that an appropriate accreditation and certification system will emphasize use of evidence-based quality improvement methodologies that use outcomes data to enhance facility processes. Within the current governmental framework exist several alternative solutions with the potential to improve the outlook for dialysis facility accreditation. One possibility involves legislative modification of the statutes that govern certification of facilities providing services to Medicare beneficiaries. By adding dialysis facilities to the list of provider types for whom certification is statutorily required (currently nursing homes and home health agencies), ESRD facilities would be assured that their certification surveys and re-inspections would both occur within a defined timeframe. Considering the highly vulnerable nature of the patient population being served by these facilities, and the potential therapeutic and economic benefits of improving care to these individuals, enactment of legislation expanding the list of Medicare providers requiring timely certification appears to be a reasonable and cost-efficient method of improving dialysis facility accreditation. The ESRD Network organizations offer another avenue for improving dialysis facility accreditation using an existing governmental agency. By providing deeming authority for certification to the Networks, HCFA would be engaging organizations that are already in contact with the nation's dialysis providers and already heavily involved in the business of improving the quality of care to ESRD patients. The territorial orientation of the network system would easily allow for consideration of regional differences as necessary. As the Networks already serve a vital role as a catalyst for improvement for the nation's

dialysis facilities, providing deeming authority to these entities would seem to be a natural extension of their current mission. The Networks are responsible for ensuring the most efficient use of Medicare dollars for dialysis treatment and kidney transplantation through monitoring quality of care indicators and maintaining timely, complete data on the ESRD program.

For these reasons, the RPA feels that the eighteen ESRD Networks are best equipped to serve as our public, quality oversight partner. In summary, we favor the ESRD Networks because of their: 1) greater depth of experience in quality oversight for ESRD patients, 2) multidisciplinary leadership of nephrologists, nurses, social workers, nutritionists, and patients, and 3) regional organization that recognizes geographic variations in care and oversight. The RPA acknowledges HCFA's quality oversight role, but feels that its size and fiduciary mission may complicate quality improvement strategies. Similarly, state health departments have substantial competing tasks that confound their role.

Recommendations

Although the RPA favors the ESRD Networks for quality oversight, we recognize opportunities to improve their quality management, and have accordingly developed the following recommendations for enhancement of the quality of delivered ESRD care. To minimize interpretive vagaries and enforce durable improvement, the RPA feels that these recommendations are best realized as a legislative mandate, such as our ESRD Continuous Quality Improvement legislative proposal.

- **Performance measures for providers and physicians should be actionable and linked to patients' outcomes.**
- **Performance of nephrologists and individual dialysis units should be routinely monitored.**
- **Minimum levels of performance should be defined and monitored using quality assurance strategies, and achievement above these minimum benchmarks facilitated using continuous quality improvement methods.**
- **Accountability should be maintained and demanded.**
- **Outcomes should be compared between providers, and appropriate results should be offered to patients.**
- **Greater coordination of efforts between oversight agencies is needed.**
- **Adequate federal funding is needed for these activities.**

Conclusion

The RPA commends the Special Committee on Aging for addressing issues surrounding the quality of care delivered to the nation's ESRD patients. We appreciate the opportunity to provide input to your efforts, and look forward to working collaboratively with the Congress to advance the goal of continuous quality improvement in the ESRD program.

APPENDIX A

Adopted by the RPA/ASN Board of Directors, 1/23/99

RPA/ASN POSITION
ON ESRD PATIENT PROTECTIONS

EXECUTIVE SUMMARY

RPA/ASN believe that in order to protect the rapidly expanding managed care population in the United States, legislation establishing patient protections must be enacted. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Foremost, the system must define and evaluate processes of enrollment and care where the patient and family understand the ramifications of a particular decision. Meaningful legislation should also include well-defined processes for quality improvement, information dissemination, and grievance resolution, protections against provider deselection, and out-of-network access, or Point-of Service (POS).

BACKGROUND

If the managed care population in the United States maintains a steady rate of growth into the next millennium as expected, it will become increasingly important that meaningful patient protections are put into place to ensure that patient health outcomes are not adversely affected by sometimes troubling managed care strategies. Recent studies indicate that while fewer than one in seven Americans with private insurance were insured by a managed care organization (MCO) less than ten years ago, today nearly three of every four Americans with private insurance are enrolled in some form of managed care. Including Medicaid and Medicare beneficiaries, there are now more than 140 million Americans covered by managed care.

RPA/ASN acknowledges that when cautiously and appropriately administered, managed care can provide enhanced efficiencies of care delivery. However, patients oftentimes get lost in the fray of efficiency and fall victim to a well-intended but flawed system. The physician must remain the patient's advocate in an increasingly sophisticated system. Early prevention can often save both costs and morbidity. For chronically ill patient populations such as those with End-Stage Renal Disease (ESRD) or those with conditions that are often precursors to ESRD such as diabetes and hypertension, the limitations inherently present in managed care can have a tangibly negative effect, including reduced quality or loss of life.

As Congress looks to address the shortcomings of managed care, we believe that certain patient protection principles of fundamental importance must be included as part of any legislative effort to reform the managed care industry. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Other critical success factors include well-defined processes for quality improvement, information dissemination, and grievance resolution, protections against provider deselection, and out-of-network access, or Point-of Service (POS). RPA/ASN believes that patient welfare and the right of physicians to provide optimal care must remain paramount within any legislative vehicle. Any compromise of those principles is unacceptable.

NECESSARY PATIENT PROTECTIONS

Access to Specialty Care

One of the most fundamental components of any managed care plan should be a guarantee of the patient's right to see a specialist with the training and experience to diagnose and manage a patient's specific medical needs. If a plan does not have an appropriate specialist in the network, it should provide for an outside referral to such a specialist, at no additional cost to the patient. The cost of delayed care may ultimately be greater than prompt care.

A common complaint with managed care organizations is that patients must make multiple requests for a referral before seeing a specialist. As a result, it can sometimes take months before an appropriate treatment plan is set in place. For patients with chronic conditions, the inability to provide timely referrals and treatment can have ramifications that last a lifetime. Such managed care policies governing access to specialty care have critical consequences for pre-ESRD and ESRD patients. Delays in the scheduling of diagnostic testing and late referrals may increase the rate of progression to chronic renal failure requiring dialysis and transplantation for patient survival. These delays can potentially become life-threatening. Late presentation of a patient with renal insufficiency restricts the nephrologists' ability to stabilize the patient's condition and provide an optimal level of care, which can delay the need for dialytic intervention or transplantation.

Similarly, because managed care organizations tend to contract with a limited number of physicians to provide dialysis, there would likely be a corresponding decrease in the number of dialysis facilities available to the patient for his or her dialysis treatments. Easy access to these facilities is critical to the successful treatment of the ESRD patient, who is often too sick to travel great distances. ESRD patients are inherently different from other health plan enrollees. Because of the life-threatening nature of their disease, ESRD patients can not be treated in the same manner as other managed care enrollees who are healthier and not in constant need of a physician's care. It seems doubtful that large health plans would take this geographic factor into account when enrolling physicians in their dialysis panels.

Therefore, RPA/ASN believes that enrollees with life-threatening, chronic, degenerative or other serious conditions that require specialized care should be provided access to an appropriate specialist or sub-specialist capable of providing quality care for that condition. If a plan does not have a participating specialist for a condition covered under the plan, the plan must refer the patient to a non-participating specialist at no additional cost. Should an enrollee have a chronic illness that requires specialty care over a long period of time, the specialist must be allowed to become the enrollee's principal care provider, thus eliminating unnecessary referrals. MCOs should have a procedure to allow individuals with serious illnesses and ongoing needs for specialty care to receive that care from a specialist -- one who will coordinate all care for that individual.

Emergency Services

Coverage of emergency care services should be based on a "prudent layperson" standard. Simply put, use of a "prudent layperson" standard would prevent the insurer, regardless of diagnosis, from denying coverage for emergency care if a "prudent layperson" would have considered the symptoms life-threatening. This "prudent layperson" standard would prevent insurers from utilizing narrowly defined categories of diagnoses when providing coverage for emergency services, and thus enable a person with an average knowledge of health and medicine to seek emergency treatment when they have a condition believed to be life-threatening.

While many managed care organizations may oppose the use of a broader definition of emergency care, implementation of a "prudent layperson" standard would encourage patients experiencing life-threatening symptoms to seek diagnosis and treatment when they might otherwise resist doing so for fear of incurring a substantial medical bill. As a result, physicians and other health care professionals would be able to treat these conditions before more serious and costly interventions are necessary.

Protection of Providers against Interference with Medical Communications And Improper Incentives

RPA/ASN firmly believes that no health plan should in any way interfere with oral and written communication between the physician and the patient. This is particularly important in the case of medical treatments that may be available for certain conditions but are expensive, require new technologies, or not regularly approved by the plan. Such protected communications should include the discussion of the patient's health status, medical care, or treatment options, provisions of the plan's utilization review requirements, or discussion of any financial incentives that may affect the treatment of the enrollee. Such prohibitions of physician-patient communications, commonly known as a "gag clauses" serve no purpose in achieving optimal health care outcomes.

Similarly, RPA/ASN believes that any patient protection legislation must include a provision prohibiting financial relationships between the insurer and the health care professional that may act as an inducement to reduce or limit medically necessary care provided to the patient. A health plan's use of financial incentives to promote efficient health care delivery via controlled utilization must not result in the withholding of medically necessary care. All medically appropriate therapeutic and diagnostic alternatives must be presented as options in keeping with the physician's primary role as patient advocate. We believe that any financial arrangement that furnishes a disincentive for providing the highest quality should be eliminated.

Quality Improvement

Managed care plans should be required to establish and maintain programs to monitor the quality of health care provided, especially with regard to at-risk or chronically ill patient populations, such as those with ESRD. Such a quality improvement program should use data based on both performance and patient outcomes. Plans should report certain standard information to state agencies and the public with accordance with uniform standards. This information should include at a minimum: utilization data, demographic data, morbidity and mortality rates, disenrollment statistics and satisfaction surveys, and quality indicators.

Under the ESRD program, the ESRD Network Organization and the United States Renal Data System (USRDS) exist to oversee the quality of care provided to ESRD patients and these groups work to improve health care outcomes. Under a system fueled mainly by MCOs, maintenance of such an effective oversight program may be problematic. Quality improvement systems are critical to the proper delivery of dialysis care. Managed care organizations may have neither the capabilities nor the disposition to provide the intensive quality agenda already being pursued by the ESRD program.

RPA/ASN believe that ideally a quality improvement process should be reiterative, with results funneled back to providers of service to facilitate enhanced performance. Such a reiterative process that recycles outcomes data back to providers of service would encourage renewed assessments of performance benchmarks, and thus foster continuous quality improvement.

Information Dissemination and Confidentiality Concerns

It is the opinion of the RPA/ASN that legislation enacted to provide patient protections must establish minimum requirements for information dissemination by health plans to enrollees. This information must address issues such as patient rights, restrictions on payments, restrictions on access to specialists, out-of-area coverage, emergency services, premiums, benefits, treatment options, covered services, patient satisfaction, grievance procedures and the results of appeals. Additionally, insurers should be

required to disseminate that information in easily understood terms so that their patients can compare the different plans and make informed choices that fits their individual needs. The purpose of such information is to facilitate the beneficiary's choice of insurer.

We also believe that in addition to the information outlined above, plans should also be required to provide procedural advice concerning cost-sharing requirements, how to obtain authorization for services, and how to get referrals to providers who may not be in the network. In other words, patients ought to have enough information at their fingertips to navigate the system without frustration and failure.

While RPA/ASN firmly supports dissemination of health plan information, we also believe that the implementation of procedures to safeguard the confidentiality of individually identifiable medical records represents a fundamentally important component of any patient bill of rights. While it is our understanding that concerns have been raised in the medical research community over the potentially dampening effect confidentiality provisions may have on research, we do not believe that these perceived competing concerns are impossible to adjudicate. Therefore, we are of the opinion that confidentiality policies compliant with all state and Federal requirements regarding medical record privacy should be included in any patient protection legislation.

Out of Network Access/Point of Service Option

In order to ensure that patients are able to receive care commensurate to their need, health plans which at the time of enrollment restrict the choice of health care professionals must establish a mechanism to allow patients to go out-of-network for treatment. Such a mechanism, often known as a point of service (POS) option, ensures that the plan have an option for the enrollee to receive benefits by a nonparticipating health care professional for an additional reasonable premium

The presence of such a vehicle providing out-of-network access can be especially crucial to achieving positive health outcomes for chronically ill patient populations. For those patients with chronic, degenerative diseases such as arthritis, diabetes or ESRD, the importance of maintaining continuity of care with the subspecialist who is not only trained to treat their condition in general but is also specifically familiar with the patient's personal history cannot be overestimated.

Provider Selection and Due Process

RPA/ASN believe that health plans should be required to establish protocols that address provider selection and allow for due process for health care professionals terminated from network participation. Such provisions would prohibit discrimination against providers when selecting for a network, set forth procedures for reasonable notice of termination, allow for review of the information leading to the termination, and outline rights of appeal for such terminated participants.

As with several of the other patient protection principles addressed above, this issue can be of particular significance to nephrologists, who treat what is arguably the sickest patient population in the Medicare universe. In addition to the high risk and high cost of treating ESRD patients, patient compliance is an important a success factor in treating ESRD. The nephrologist's ability to affect a positive result is highly contingent upon the patient's cooperation. The confluence of these circumstances could foster an environment where subspecialists treating chronically ill patients would be subject to deselection.

Grievance Procedures

RPA/ASN believe that insurers must establish meaningful internal and external grievance procedures to act as a final "backstop" in ensuring adequate patient protections. Internally, procedures should establish the patient's right to appeal denials of care and to voice concerns regarding the health plan, and should require the plan to have appeals heard in a timely manner by appropriately credentialed individuals. Externally, for cases of sufficient seriousness or beyond an established monetary threshold, individuals must have access to an external, independent body with the capability and authority to resolve such grievances. Such a body for ESRD patients must include nephrologists.

Under current law enrollees are allowed to appeal their health plan's decision with regard only to the denial of care through an internal process. Such a system gives the insurer the right to decide what care should or should not be provided. We believe that a more appropriate process of appeal would address all aspects of the plan's services, including complaints regarding the quality of care, choice and accessibility of providers, and network adequacy. A two-stage appeal process should be implemented, with requirements initially for a review panel of non-involved providers, and an independent body in the second phase. A written explanation of each phase must be provided and timely decisions are required.

RECOMMENDATIONS

RPA/ASN's firmly believes that purposeful reform of the managed care industry is necessary to protect the exponentially growing number of participants in managed care plans, especially those with chronic illnesses such as ESRD.

RPA/ASN believe that legislation in this area that addresses the following fundamental issues will accomplish such reform.

- **Access to Specialty Care** - RPA/ASN believes that enrollees with life-threatening, chronic, degenerative or other serious conditions that require specialized care should be provided access to an appropriate specialist capable or providing quality care for that condition. Frequently, patients in managed care must make multiple requests before seeing a specialist. For patients with chronic conditions, the inability to provides timely referrals and treatment can have ramifications that last a lifetime, particularly for pre-ESRD and ESRD patients. Delays in the scheduling or diagnostic testing and late referrals may increase the rate of progression to chronic renal failure requiring dialysis and transplantation for patient survival. These delays can be potentially life-threatening.

- **Emergency Services** - Coverage for care should be based on a "prudent layperson" standard. The use of a "prudent layperson" standard would prevent the insurer, regardless of diagnosis, from denying coverage of emergency care if a "prudent layperson" would have considered the symptoms life-threatening.

- **Protection of Providers against Interference with Medical Communications and Improper Incentives** - RPA/ASN firmly believes that no health plan should interfere with oral and written communication between the physician and the patient. Such protected communications should include the discussion of the patient's health status, medical care, or treatment options, provisions of the plans utilization review requirements, or discussion of any financial incentives that may affect the treatment of the enrollee. Similarly, patient protection legislation must include a provision prohibiting financial relationships between the insurer and the health care professional that may act as an inducement to reduce or limit medically necessary care provided to the patient.

- **Quality Improvement** - Managed care plans should be required to establish and maintain programs to monitor the quality of health care provided, especially with regard to at-risk or chronically ill patient populations, such as those with ESRD. Quality improvement programs

should use data based on both performance and patient outcomes.

- **Information Dissemination and Confidentiality Concerns -** Patient protections legislation must establish minimum requirements for information dissemination by health plans to enrollees. Information must address issues such as patient rights, restrictions on payments, treatment options, restrictions on access to specialists, out-of-area coverage, emergency services, premiums, benefits, covered services, patient satisfaction, grievance procedures, and the results of appeals.

- **Out of Network Access/Point of Service Options** - Health plans which at the time of enrollment restrict the choice of health care professionals must establish a point of service (POS) option, a mechanism to allow patients to go out-of-network for treatment. The presence of such a vehicle providing out-of-network access can be especially crucial to achieving positive health outcomes for chronically ill patients such as those suffering from ESRD. The importance of maintaining continuity of care with the subspecialist who is not only trained to treat their condition in general but is also specifically familiar with the patient's personal history cannot be overestimated.

- **Provider Selection and Due Process** - Health plans should be required to establish protocols addressing provider selection and allow for due process for health care professionals terminated from network participation. Such provisions would prohibit discrimination against providers when selecting for a network, set forth procedures for reasonable notice of termination, allow for review of the information leading to termination, and outline rights of appeal for such terminated participants.

- **Grievance Procedures** - Insurers must establish internal and external grievance procedures to ensure adequate patient protections. Internally, procedures should establish the patient's right to appeal denials of care and to voice concerns regarding the health plan, and should require the plan to have appeals heard in a timely manner by appropriately credentialed individuals. Externally, for cases of sufficient seriousness or beyond an established monetary threshold, individuals must have access to an external, independent body with the capability and authority to resolve such grievances.

Congress should maintain passage of patient protection legislation as its highest priority.

APPENDIX B

RPA Principles on ESRD Patient Participation in Managed Care

RPA opposes a repeal of Section 1876 of the Social Security Act, which specifically prohibits Medicare ESRD beneficiaries from participating in managed care plans. The issue of ESRD patient participation in managed care plans has recently come under increased scrutiny, and therefore RPA believes this subject merits reevaluation. Results of recent studies conducted by HCFA, while still awaiting rigorous validation, fail to confirm that ESRD patients would experience adverse outcomes in managed care delivery systems. Other relevant literature indicates that vulnerable patient groups such as those with ESRD would require special treatment in managed care settings. This divergence of data demonstrates a need for further study of these issues.

As noted in the RPA/ASN Position Paper on "Managed Care and Nephrology", legislative proposals that focus on the subject of allowing ESRD patients to enter managed care environments must address the following issues:

- A quality oversight program must be implemented that includes continuous quality improvement methodologies such as clinical practice guidelines, clinical performance measures, and integrated information systems. Quality improvement processes should encompass the current ESRD Network system and should focus on actual implementation of CQI methodologies at both the Network level and the facility level. A national committee should be established to oversee these CQI efforts. Legislative proposals should include emphasis on patient surveys and outline the critical success factors needed for QI implementation at the network and dialysis facility level.

- Public and private sector funding must be obtained to support this initiative, including contributions from private plans covering ESRD patients during their 30 month waiting period for entrance into the Medicare ESRD program, and contributions to Network activities by the Medicaid program.

- ESRD patients must have access to the level of specialty care necessary to treat their condition.

- ESRD patients must be afforded the following protections if and when they are allowed to enter managed care: a. receive easy to understand marketing information; b. receive information on plan enrollment and disenrollment; c. access to a prudent layperson standard for emergency medical care; and d. access to an efficient and effective appeals process.

- Modification of the AAPCC must occur first as many of the other difficulties occurring in Medicare managed care flow from inadequate reimbursement for these groups of patients. Appropriate adjustment for case-mix variability that provides sufficient reimbursement for both complex and relatively stable ESRD patients will allow the sponsors of these delivery systems to provide an expanded level of benefits to vulnerable patients while maintaining fiscal viability. RPA suggests including an analysis of the potential impact of AAPCC changes with specific emphasis on determining what level of risk for providers is appropriate and how this level of risk will affect the treatment of the sickest ESRD sub-populations. Such an analysis should also address a study of Medicare patients not part of the ESRD program, and AAPCC methodologies outside the ESRD milieu.

- The nephrologist's ability to function autonomously within the current system must be preserved. This autonomy should maintain the nephrologist's freedom in clinical decision making and foster the nephrologist's position as the leader of the renal care team.

- The nephrologist's ability to negotiate contracts, achieve appropriate reimbursement for their services, and develop relationships with the other essential participants in a capitated payment system must be preserved.

- The outcomes from HCFA's ESRD Managed Care Demonstration Project must be considered in developing a legislative policy that affects ESRD patient enrollment in managed care.

- Any legislative proposal to repeal the 1876 prohibition must be delayed for a minimum of two years to allow for modification of the AAPCC and full implementation of the CQI oversight program. In the event that the AAPCC and CQI proposals are not implemented, the ban must not be repealed.

APPENDIX C

REVISED DRAFT, 3/2000

Adopted by the RPA/ASN Board of Directors, 4/14/97

RPA/ASN POSITION ON IMPROVING ACCREDITATION OF DIALYSIS FACILITIES

Executive Summary

The RPA/ASN supports the accreditation, certification and licensure of dialysis facilities as a visible means of insuring accountability, and that in order to accomplish these functions appropriately, increased federal funding is necessary. The RPA/ASN supports public and private sector efforts to accredit and/or certify dialysis facilities provided an appropriate process and methodology are established and provided the renal community has appropriate and reasonable participation. The RPA/ASN believe that an appropriate accreditation and certification system will emphasize use of evidence-based quality improvement methodologies that use outcomes data to enhance facility processes. The RPA/ASN believes that legislation should be enacted to expand deemed certification, with appropriate safeguards, to include ESRD providers, and that the certification process must be unified among the various levels of government to avoid duplication and eliminate unnecessary expense to dialysis facilities.

Background

Over the past decade, the number of Americans requiring treatment for End Stage Renal Disease (ESRD) has experienced significant continual growth. According to data released by the Health Care Financing Administration (HCFA), more than 361,000 patients were receiving treatment under the Medicare program for ESRD (as of 12/31/97), with an approximate annual rate of growth of 8 percent. Consistent expansion of the kidney failure patient population heightens the challenges facing the nation's renal care community in their efforts to provide the highest possible level of care to an extremely vulnerable group of patients.

A key component of high quality ESRD patient care is the availability of accredited facilities providing dialysis services. However, the current accreditation process has often worked against optimal dialysis facility availability. Improvements in the accreditation process are needed to enhance patient convenience and therefore facilitate compliance, which is arguably equal to or more important in the treatment of chronic kidney disease than any other medical condition. Increasing access to dialysis facilities and thereby reducing the hardships that excess travel time places on patients is critically important to improving outcomes. Patient non-compliance invariably jeopardizes the adequacy of their dialysis and leads to infection, increased co-morbidities and ultimately loss of life. Financially, non-compliant dialysis patients escalate the burden on an already stressed health care system by increasing the likely necessity of emergency dialysis, surgery, and hospitalization. However, as dialysis centers become more accessible, treatments become less burdensome on patients' time, more economical, and more conducive towards the maintenance of a predialysis lifestyle and employment, with improved patient outcomes.

On a positive note, the issue of dialysis facility accreditation has garnered the attention of health care policymakers in recent years, and as a result several efforts are underway to examine and enhance the methodologies under which this accreditation occurs. Foremost among these initiatives is a 1997 study performed by The Lewin Group and Johns Hopkins University in response to a HCFA RFP to review the Medicare survey and certification process for dialysis facilities. Included among the study's recommendations were:

- The success of the accreditation process is dependent upon increased funding, and reallocation of those funds.

- Increased uniformity of the inspection process is necessary, with particular emphasis on frequency and training of inspectors. The goal for inspection frequency should be once every 1-2 years, and implementation of uniform processes for collection and analysis of outcomes data and data sharing must be established.

- Accreditation survey content must be standardized.

- Communications and cooperation from all stakeholders in the process is necessary.

Complimenting the Lewin study is a HCFA sponsored effort to develop a dialysis facility-specific data report for use by state surveyors. This project is intended to fulfill a legislative mandate set by the Balanced Budget Act of 1997 (BBA '97) to develop a method for assessing the quality of care delivered to Medicare's ESRD beneficiaries, and was managed under contract by the Colorado Foundation for Medical Care (CFMC). The initiative seeks to use existing databases to develop user-friendly facility-specific profiles based on an outcome-oriented approach. Other HCFA activities in this area include the Agency's ongoing efforts to continually improve ESRD care through the ESRD Core Indicators Project and its Health Care Quality Improvement Program. Finally, the Office of the Inspector General (OIG) issued a report on the Medicare certification process that, while primarily focusing on hospitals and nursing homes, does confirm the lack of resources available for dialysis facility certification and accreditation.

RPA/ASN strongly supports the accreditation, certification and licensure of dialysis facilities as a necessary and visible method of insuring public accountability, and as such we believe the public sector efforts to examine these issues represent a positive step toward improving dialysis facility accreditation. However, we continue to believe that the current process is fraught with problems and compromises the ability of nephrologists to provide the highest level of quality patient care possible. This paper will discuss the current accreditation system and its limitations, and analyze both the merits of improving accreditation within the current governmental framework, and the potential of private accreditation of dialysis facilities. Further, the paper will offer recommendations on how to ensure accountability using this methodology, and discuss the accreditation process and its effect on renal care delivery.

Dialysis Facility Accreditation: Current Situation

Under the current system, dialysis facilities are accredited through a federally-funded block grant program intended to ensure that institutions and agencies providing care to Medicare and Medicaid beneficiaries meet all federal health, safety and program standards. Federal funds are provided to each state. State surveying agencies then conduct on-site surveys, which are randomly monitored by federal surveyors. This fragmented execution of the certification process is the source of many of the current system's difficulties. Two significant problem areas are the irregular distribution and dispersal of federal funds and the inconsistent, "patchwork" nature of the actual surveying process, both circumstances being a function of 50 separate state government entities carrying out certification duties.

One result of budgetary constraint and enormous expansion of the health care industry is the lack of financial resources to achieve appropriate licensure of institutions serving the Medicare/Medicaid population. Out of the pool of money provided to each state for inspection of facilities providing care to these beneficiaries, the states are responsible for certifying or accrediting a wide range of health care providers. Included on this list are home health agencies, nursing homes, ambulatory surgical centers, rural health clinics, and numerous others, in addition to dialysis facilities. To further exacerbate the

accreditation outlook for institutions providing ESRD services, inspection of two of the provider types on the list, home health agencies and nursing homes, is statutorily required and therefore must be performed before any other surveys take place. As a result, ESRD facilities are competing with all of the other types of institutions providing care to Medicare/Medicaid beneficiaries (about ten provider types) for the funds remaining from the federal certification grant to each state. Consequently, new dialysis facilities can sit idle for months before receiving their initial certification, and existing centers often go years between their subsequent inspection surveys. Patient care is jeopardized by forcing chronically ill recipients of dialysis services to travel significant and unnecessary distances to receive treatment while a nearby center awaiting accreditation sits unutilized (thus reducing patient compliance), or by allowing problems that do arise at previously accredited, "good" facilities to remain uncorrected.

The current system also often allows the quality of the surveys that do occur to be compromised. Lack of uniformity in the training and education of the surveyors causes great variability in the caliber of inspections from state to state. While the dialysis facility certification process in some states is a positive and educational exercise that fosters the development of effective processes of patient care at the institution, in other states accreditation inspections can be arbitrary and punitive, and contrary to the needs of the local kidney patient population. A common complaint is that the primary training of the inspectors performing surveys at dialysis facilities is geared towards inspecting nursing homes or home health agencies, rendering the inspectors uninformed about the nuances of dialytic care. Some dialysis unit medical directors have noted that surveyors unfamiliar with renal care processes will often focus on issues peripheral to dialysis delivery while ignoring the more critical elements of ESRD services, or will cite the facility for "violations" that do not reflect deviation from the state regulations governing ESRD facilities.

In spite of the efforts of HCFA and the state regulatory agencies to ensure that providers of dialysis services receive both initial accreditation and recertification on a timely and intelligent basis, the current system is at best inconsistent and at worst reduces the adequacy of the patient's dialytic care. The RPA/ASN believes that it is appropriate to explore new methods of accrediting the nation's dialysis facilities, whether through the framework of the present governmental system or through the use of private accrediting bodies (under the Medicare deemed status program). Accordingly, RPA/ASN is supportive of HCFA's efforts to review the requirements and methodologies associated with the accreditation and certification of dialysis facilities.

Use of Existing Structures

Within the current governmental framework exist several alternative solutions with the potential to improve the outlook for dialysis accreditation. One possibility involves legislative modification of the statutes that govern certification of facilities providing services to Medicare beneficiaries. By adding dialysis facilities to the list of provider types for whom certification is statutorily required (currently nursing homes and home health agencies), ESRD facilities would be assured that their certification surveys and re-inspections would both occur within a defined timeframe. Considering the highly vulnerable nature of the patient population being served by these facilities, and the potential therapeutic and economic benefits of improving care to these individuals, enactment of legislation expanding the list of Medicare providers requiring timely certification appears to be a reasonable and cost-efficient method of improving dialysis facility accreditation.

The ESRD Network organizations offer another avenue for improving dialysis facility accreditation using an existing governmental agency. By providing deeming authority for certification to the Networks, HCFA would be engaging organizations that are already in contact with the nation's dialysis providers and already heavily involved in the business of improving the quality of care to ESRD patients. The territorial orientation of the network system would easily allow for consideration of

regional differences as necessary. As the Networks already serve a vital role as a catalyst for improvement for the nation's dialysis facilities, providing deeming authority to these entities would seem to be a natural extension of their current mission. The Networks are responsible for ensuring the most efficient use of Medicare dollars for dialysis treatment and kidney transplantation through monitoring quality of care indicators and maintaining timely, complete data on the ESRD program.

Advantages of Private Accreditation of Dialysis Facilities

The concept of private sector accreditation of health care providers serving Medicare beneficiaries is time-tested and valid, and would provide substantial benefit to the ESRD community. The federal government acknowledged the merits and benefits of this licensure method when it created the Medicare deemed status program. A key factor in granting an accrediting body deeming authority is HCFA's determination that the organization's standards are equivalent to or more stringent than federal health, safety and program regulations. Once the deeming authority has been granted to providers serving the Medicare ESRD population and the public/private sector partnership has been forged, significant benefits would be realized, including:

- Private accrediting organizations would assist the federal government in the enormous task of certification of new dialysis facilities and re-certification of existing ones, greatly reducing both the backlogs in these areas and federal regulatory expenditures.

- Improved quality of patient care would invariably result from the higher standards in some areas that accrediting organizations would bring to the process and an overall cross-fertilization of accrediting methodologies.

- Private sector resources would produce inspectors well-trained in the specifics of ESRD care, leading to a reorientation of the certification process towards an educational model that would foster facility development.

- Participants would reap economic benefit as the costly delays previously experienced in opening new dialysis facilities would be eliminated; the possibility that Medicare will enact user fees for certification in the future increases the potential for cost savings.

- Providers of ESRD care would be granted access to the same types of accreditation that other health care providers have utilized for years.

Accountability and Unification

In order to earn HCFA deeming authority, the RPA/ASN believes that an applicant dialysis facility accrediting organization must demonstrate accountability for its actions, and develop appropriate methodologies and standards. In addition to demonstrating that its standards are equivalent to or more stringent than HCFA standards, the applicant should develop a comprehensive reporting mechanism and establish a framework for a partnership with HCFA and the National Renal Coalition. Among the elements of the partnership should be:

- Notification of survey schedules to HCFA.

- Random inspections of a percentage of accredited facilities by HCFA for validation by qualified inspectors.

- Reports to HCFA on dialysis facilities with demonstrated deficiencies, particularly regarding water treatment and reuse, as these activities are often the source of deficiencies.

- Notification to HCFA of any dialysis facilities whose processes pose a danger to the patient's health or public safety.

- Notification to HCFA of all newly accredited dialysis facilities, and all facilities whose accreditation has been denied or suspended.

To develop appropriate survey methodologies and standards, the RPA/ASN believes that it is necessary to incorporate multidisciplinary input from all members of the national renal community. The methodologies and standards developed should be as scientifically valid and as clinically relevant as possible, with a clear link to continually improving facility performance and thus positively affecting patient outcomes. Additionally, the surveys should be as non-intrusive as possible.

One of the common complaints about the current process relates to the duplication among the various jurisdictions certifying dialysis facilities, and opponents of private accreditation feel that it will result in an additional layer of expense. Therefore, a crucial element to the success of private accreditation efforts is the unification of the certification process so that licensure criteria of all affected governmental entities (national, regional, state, local) are satisfied. It is the opinion of the RPA/ASN that the criteria for granting HCFA deemed status to dialysis facilities must be designed in such a way to meet the standards of the other governing bodies and avoid duplication of certification efforts. HCFA oversight of the accreditation process is needed to ensure public accountability and allow the unification of the process so that state licensure requirements can be eliminated. Unifying the survey and certification process will help eliminate the duplication and additional expense, simplify multiple governmental standards, and ease the regulatory burden on providers of ESRD services while improving patient outcomes. Precedent does exist for recognition of HCFA-approved accrediting bodies for state licensure purposes. The states of Oregon and Florida have recognized the Commission on Office Laboratory Accreditation (COLA) for licensure of physician office laboratories (POLS).

Recommendations

- **The accreditation or certification of dialysis facilities is a visible mechanism of insuring public accountability. Therefore, RPA/ASN supports accreditation and certification, as well as licensure, of dialysis facilities.**

- **RPA/ASN believe that in order to achieve appropriate accreditation and certification of the nation's dialysis facilities, increased federal funds be provided to HCFA by Congress, and reallocation of those funds by HCFA must be considered.**

- **RPA/ASN believe that as methods for enhancing the accreditation and certification of the nation's dialysis facilities are evaluated and developed, evidence-based quality improvement methodologies that use outcomes data to enhance facility operations should be emphasized.**

- **RPA/ASN supports the development and enactment of legislation that would expand deemed certification for ESRD providers, with appropriate safeguards.**

- **Public and private sector efforts to accredit and/or certify dialysis facilities can be supported provided an appropriate process and methodology are established and provided the renal community has appropriate and reasonable participation.**

- **If multiple entities and both public and private entities accredit or certify dialysis units, these efforts should be substitutive rather than duplicative. Private sector initiatives to accredit or certify dialysis facilities, subject to oversight by HCFA, must replace the Medicare certification process and the state licensure process, the former under the Medicare deemed status program.**

- **The process for developing accrediting standards should be undertaken with appropriate input from all involved parties, including the member organizations of the National Renal Coalition, the regional ESRD Networks, and representatives or designees from HCFA.**

- **The methodologies, standards, and measures established by both public and private sector entities to review and accredit dialysis facilities should be scientifically valid, ensible, uniform, and as non-invasive and non-intrusive as possible. Both public and private sector accreditation/certification initiatives should be subjected to reasonable cost benefit analyses.**